DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 15, 2015

La Lumiere, LLC
% M. Joyce Heinrich
Texas Applied Biomedical Services
12101 Cullen Boulevard, Suite A
Houston, Texas 77047

Re: K140471
Trade/Device Name: Pro X OTC 5 Light Therapy Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: December 29, 2014
Received: December 31, 2014

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140471

Device Name
Pro X OTC 5 Light Therapy Device

Indications for Use *(Describe)*
The Pro X OTC 5 is an Over-The-Counter device intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have Fitzpatrick skin types I, II and/or III.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for Pro X OTC 5 Light Therapy Device

1. Submission Sponsor

LaLumiere, LLC

2. Submission Correspondent

Texas Applied Biomedical Services (T.A.B.S.)
12101 Cullen Blvd, Suite A
Houston, Texas 77047
Phone: (713) 734-4433
Fax: 1-866-362-3968
Contact: M. Joyce Heinrich, President

3. Date Prepared

15 January 2015

4. Device Name

Trade/Proprietary Name: Pro X OTC 5
Common/Usual Name: Wrinkle Light Therapy System
Classification Name: Light Based Over- the-Counter Wrinkle Reduction
Classification Regulation: 21CFR 878.4810
Classification Panel: General and Plastic Surgery
Product Code: OHS
Device Class: II
FDA Establishment Registration #: To be obtained after clearance

5. Predicate Devices

Lightstim for Wrinkles (K120775) manufactured by LED Intellectual Properties, LLC; illuMask Acne Mask (K123999) manufactured by La Lumiere, LLC.

6. Device Description

The Pro X OTC 5 is an Over-the-Counter device intended for use in the treatment of facial wrinkles. Facial wrinkles are lines on the skin that appear as you age. Facial wrinkles can appear anywhere on the face, such as on the forehead, around the eyes, and by the mouth. The Pro X OTC 5 is for people with wrinkles on their face and who have Fitzpatrick skin types I, II, and/or III.

The Pro X OTC 5 uses known LED light therapy technology. A combination of red light (620-630nm) and infrared light (855nm) is emitted. To use the Pro X OTC 5 device, users place the lightweight mask over the face and then press the "On" button on the controller to start treatment. The device will automatically turn off after each treatment cycle.

The Pro X OTC 5 device is designed to be used for 30 treatment sessions. The full treatment regimen for facial wrinkles includes 60 individual treatments, therefore purchase of two (2) devices is needed to receive the full treatment regimen.

Technical Specifications

Parameter	Specification
Wavelengths of: **Red light** **Infrared light**	 **620-630 nm** **855 nm**
Power Density (mW/cm^2): **Red light** **Infrared light**	 **.016** **.0029**
Total Dose Energy (J/cm2) / 60 Treatments: **Red light** **Infrared light**	 **0.86** **0.16**
Overall Total Energy (J) / 60 Treatments	**332**
Individual Treatment Time (seconds)	**900**
Total Treatments per Full Treatment Regimen	**60**
Treatment cycles per device	**30**

7. Intended Use

The Pro X OTC 5 is an Over-The-Counter device intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have Fitzpatrick skin types I, II and/or III.

8. Non-Clinical Testing

The Pro X OTC 5 device conforms to the requirements of IEC 60601-1 3rd edition, IEC 60601-1-2, and IEC 62471.

Additionally, the Pro X OTC 5 Device was evaluated by the typical layperson in two separate studies: 1) Usability Study and 2) Self-Selection Study. The Usability Study was developed and conducted with 20 participants randomly selected from the general public representative of the population to which the Pro X OTC 5 Device is intended to be marketed to. This study evaluated the labeling aspects of the device to determine the understanding of the naïve layperson that are representative of the adult population for which the device is marketed.

The overall results of the Usability Study demonstrated that the participants in this study successfully completed the evaluation of the three major aspects of the study design: 1) outer packing and box label, 2) Instructions for Use (manual included inside the packaging), and 3) use of the device by laypersons.

The objective of the Self-Selection study was to evaluate the external packaging (box labeling) of the Pro X OTC 5 device by the naïve layperson to determine if there is sufficient information visible for them to decide (self-select) whether or not to use the device. A total of 20 participants, ranging in from 18 years and older, were randomly asked to review the external package labeling of the Pro X OTC 5 and complete a questionnaire at the end of their review. The results of this study demonstrated that the external packaging is in a language that is fully understood by a randomly selected group of naïve laypersons that are representative of the adult population for which the device is marketed.

9. Clinical Testing

An 8-week clinical study was conducted with 50 subjects with Fitzpatrick Skin types I – III, 30 of which were randomly assigned into the Treatment Group and used the Pro X OTC 5, and 20 of which were randomly assigned into the Control Group and used a placebo mask. All subjects underwent an eight (8) week treatment regime followed by a 3-month post treatment (20-weeks) evaluation. The subjects used the device for 60 times during the 8 weeks period.

Standardized facial photographs were made at baseline and each subsequent evaluation period. The device was used by the subjects for 8 weeks and the last assessment photos were taken 3 months after the last treatment. The photographs were evaluated by two independent, blinded, licensed physicians using the 9-point Fitzpatrick Wrinkle and Elastosis Scale. The statistical analysis of the outcome measure of wrinkles demonstrated that the Pro X OTC 5 Device is effective in the treatment of facial wrinkles.

The Treatment Group demonstrated absolute improvement in the Fitzpatrick scores for both physicians at all evaluation periods. For Physician 1 the mean baseline grade was 5.10, and after 8-weeks the

grade was 3.86, a difference of 1.24 points. At the 20-weeks post treatment evaluation, further reduction was realized with a grade of 3.83, a difference of 1.28-points from baseline. For Physician 2 the mean baseline grade was 5.03, and after 8-weeks the grade was 3.83, a difference of 1.21 points. At the 20-weeks post treatment evaluation, further reduction was realized with a grade of 3.90, a difference of 1.14-points from baseline. Each subject demonstrated at least 1 point improvement individually based on the comparison between baseline and 20-weeks post treatment follow up pictures.

The Treatment Group showed statistically significant improvement in Fitzpatrick score at all evaluation periods, whereas, the Control Group did not show statistically significant improvement in the Fitzpatrick Score at any evaluation period.

The Treatment Group statistically significantly outperformed the Control Group at all evaluation periods; 8-weeks and 20-weeks evaluation for both physicians, $p<0.001$.

10. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regards its safety and effectiveness as compared to the predicate device.

We have shown in this 510(k) submission that the Pro X OTC 5 has the same intended use and technological characteristics as the predicate devices and does not raise any questions regarding its safety and effectiveness. The Pro X OTC 5 device, as designed and manufactured, has been found to be substantially equivalent to the predicate devices.